BIOMET®
MANUFACTURING CORP.

510(k) Summary

Preparation Date: October 19, 2007

NOV - 5 2007

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Becky Earl

Proprietary Name: Regenerex™ Porous Titanium Sleeve Augments

Common Name: femoral and tibial knee augments

Classification Name(s):

- Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (888.3560)
- Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis (888.3565)
- Knee joint femorotibial metal/polymer constrained cemented prosthesis (888.3510)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Regenerex™ Knee Augments (Biomet, Inc.)- K053505 and Trabecular Metal™ Tibial and Femoral Cone Augments (Zimmer, Inc.)- K053340

Device Description: The Regenerex™ Porous Titanium Sleeve Augments are truncated cones with a centrally located bore that are composed of titanium alloy (Ti-6Al-4V) per ASTM F1580-95 that is approximately 67% porous. The augments are designed for attachment to selected commercially available Biomet® tibial base plates and stemmed femoral components using cement. The devices are intended for fixation into either the proximal tibia or distal femur in cases of severe bone loss.

Indications for Use:

The Regenerex™ Porous Titanium Sleeve Augments (Femoral and Tibial Sleeve Augments) are indicated for use with the following cemented systems: the Vanguard™, Ascent™, and Maxim® knee systems, as well as the Biomet® Tibial Augmentation Components, Stemmed Tibial Components, Offset Tibial Trays and Offset Tibial Tray Adaptors. The Regenerex™ Porous Titanium Sleeve Augments are indicated for use with following uncemented system: the Vanguard™ Non-Cemented Porous Coated Knee Components.

Specific indications are as follows:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

These are single use implants.
Cemented and uncemented applications.

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587
Toll Free: 800.348.9500
Office: 574.267.6639
Main Fax: 574.267.8137
www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

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and

The Regenerex™ Porous Titanium Sleeve Augments (Femoral and Tibial Sleeve Augments) are indicated for use with the OSS™ system.

Specific indications are as follows:

1. Painful and disabled knee joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis, or traumatic arthritis.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
4. Ligament deficiencies.
5. Tumor resection.
6. Trauma.

These are single use implants.
Cemented applications only.

Summary of Technologies: The technological characteristics (material modification, design, sizing, indications) of the Regenerex™ Porous Titanium Sleeve Augments are similar to or identical to the predicate devices.

Non-Clinical Testing: Previous non-clinical laboratory testing and engineering justification was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2007

Biomet Manufacturing Corp.
% Ms. Becky Earl
Regulatory Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K072336
Trade/Device Name: Regenerex™ Porous Titanium Sleeve Augments
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, MBH, KRO
Dated: October 19, 2007
Received: October 22, 2007

Dear Ms. Earl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

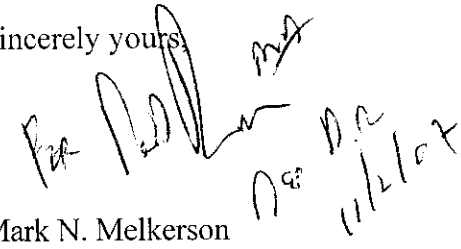
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072336

Device Name: Regenerex™ Porous Titanium Sleeve Augments (Femoral and Tibial Sleeve Augments)

The Regenerex™ Porous Titanium Sleeve Augments (Femoral and Tibial Sleeve Augments) are indicated for use with the following cemented systems: the Vanguard™, Ascent™, and Maxim® knee systems, as well as the Biomet® Tibial Augmentation Components, Stemmed Tibial Components, Offset Tibial Trays and Offset Tibial Tray Adaptors. The Regenerex™ Porous Titanium Sleeve Augments are indicated for use with following uncemented system: the Vanguard™ Non-Cemented Porous Coated Knee Components.

Specific indications are as follows:

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2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

These are single use implants.
Cemented and uncemented applications.

Prescription Use YES AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

K072336

Indications for Use

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The Regenerex™ Porous Titanium Sleeve Augments (Femoral and Tibial Sleeve Augments) are indicated for use with the OSS™ system.

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3. Correction or revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
4. Ligament deficiencies.
5. Tumor resection.
6. Trauma.

These are single use implants.
Cemented applications only.

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)